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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,435	11/30/2004	Joseph P. Orban III	2823	3071
Covidien 60 Middletown Avenue North Haven, CT 06473	7590 12/27/2007		EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 12/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/516,435	Applicant(s) ORBAN III ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 16-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/18/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 13 and base claim 14, "the rigid annular ring" lacks antecedent basis. Also with respect to claim 14, "the spaces of the annular support structure" lacks antecedent basis.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3, 6-10, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahlke et al. (4,796,603). Dahlke et al. disclose, at least in fig. 3 and in col. 2, lines 50-66; col. 3, lines 29-42, and col. 4, lines 17-43; a support structure

including an annular ring (2) having an outer annular wall with a diameter, an inner annular wall spaced a radial distance inward of the outer inner wall and defining a space, a upper wall, a lower wall; the outer and inner annular walls and the upper and inner walls defining a reservoir, and wound closure material (e.g., a polyglactin and/or tissue fluid) releasable from the reservoir (i.e., the wound closure material is released from permeation through the annular walls and through resorption by surrounding tissue, where resorption is a form of release of the wound closure material—see also col. 2, line 60 to col. 3, line 7) ; where the annular ring has circular cross-sectional profile, where the wound closure material is a hemostat or a sealant that is a synthetic polymer-based material, where the annular outer and inner walls comprise a rigid material that is bioabsorbable (e.g., polyglactin), where the annular ring comprises a plurality of interstitial spaces (between fibers or filaments) configured and adapted to allow staple legs to pass through (if so desired).

5. Claims 1, 10, 11, 14, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuslich (6,712,853). Kuslich disclose, at least in fig. 4 and in col. 8, lines 39-52; col. 9, line 49 to col. 10, line 17; and col. 13, lines 44-48; a support structure including an annular ring (e.g., 12) having an outer annular wall with a diameter, an inner annular wall spaced a radial distance inward of the outer inner wall and defining a space, a upper wall, a lower wall; the outer and inner annular walls and the upper and inner walls defining a reservoir, and wound closure material releasable from the reservoir (e.g., “fluids and solutions” or “therapeutic agents”), where the annular outer and inner walls comprise a rigid material that is stainless steel or titanium, and where

the annular ring includes cartridge orientation members or a plurality of nubs (i.e., small projections as formed at the intersections of woven filaments, which produce "pores or weave gaps" that can receive staples).

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lambe (3,022,810). Lambe discloses, at least in the figures and in col. 4, line 35 to col. 5, line 15; a support structure including an annular ring having an outer annular wall (10) with a diameter, an inner annular wall (13) spaced a radial distance inward of the outer inner wall and defining a space, an upper wall (side of 10), a lower wall (side of 10); the outer and inner annular walls and the upper and inner walls defining a reservoir, and wound closure material (11—a synthetic polymer-based material) releasable from the reservoir (through a "tube and valve (not shown)" before curing of the material).

7. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Britz (4,909,972). Britz discloses, at least in figure 1 and in col. 5, lines 16-36; a support structure including an annular ring (10) having an outer annular wall (18) with a diameter, an inner annular wall (14) spaced a radial distance inward of the outer inner wall and defining a space, an upper wall (side of 18), a lower wall (side of 18); the outer and inner annular walls and the upper and inner walls defining a reservoir, a wound closure material (a synthetic polymer-base material), and at least one removable support spoke (12).

8. Note: The introductory statement of intended use ("for use in conjunction with a circular endoscopic stapling instrument having a staple cartridge assembly and an anvil assembly, the staple cartridge assembly having at least one annular arrangement of

staple slots and staples positioned in the slots, wherein the support structure maintains a resulting anastomotic lumen in an open condition") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the devices of Dahlke et al., Kuslich, Lambe, and Britz, which are capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlke et al. (4,796,603). Dahlke et al. disclose the invention substantially as claimed, but do not disclose the diameters of the outer and inner annular walls as claimed. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to size the annular walls as claimed, since such modifications would have

involved mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

11. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Britz (4,909,972) in view of Lambe (3,022,810). Britz discloses the invention substantially as claimed, but does not disclose a wound closure material releasable from the reservoir. Lambe teaches a wound closure material injectable and releasable from a reservoir analogous to the reservoir of Britz. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Lambe, to modify the support structure of Britz, so that the wound closure material is releasable from the reservoir. Such a modification would allow adjustment of the volume and pressure of wound closure material and air injected into the reservoir, and it would allow in-situ filling of the reservoir (i.e., between the outer and inner annular walls).

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Britz in view of Lambe as applied to claim 4 above, and further in view of James (4,231,407). Britz in view of Lambe discloses the invention substantially as claimed. The combination discloses a support structure with a central hub. However, the combination does not disclose that the hub includes a central axial opening that is configured and dimensioned to receive the shaft of the anvil assembly. James teaches, in figure 3, a support structure with a central hub having a central axial opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of James, to include a central axial opening in the central hub of Britz in view of

Lambe. Such an opening would allow the support structure to accommodate an axle for rotation of the support structure and connection to a vehicle.

13. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Britz in view of James (4,231,407). Britz discloses the invention substantially as claimed. However, Britz does not disclose that the hub includes a central axial opening that is configured and dimensioned to receive the shaft of the anvil assembly. James teaches, in figure 3, a support structure with a central hub having a central axial opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of James, to include a central axial opening in the central hub of Britz. Such an opening would allow the support structure to accommodate an axle for rotation of the support structure and connection to a vehicle.

Response to Amendment

14. Applicant's arguments filed on September 28, 2007 have been fully considered but they are not fully persuasive or are moot in view of new grounds of rejection. With respect to arguments regarding the rejections based on the Dahlke and Kuslich references: Dahlke and Kuslich indeed disclose support structures including wound closure materials releasable from their respective reservoirs as pointed out above. The rejection of claim 2 under 35 U.S.C. 112, 2nd paragraph, is hereby withdrawn.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wong (4,286,587) and Agudisch et al. (5,788,977) teach annular support structures with reservoirs.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Application/Control Number:
10/516,435
Art Unit: 3773

Page 9

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Julian W. Woo". The signature is written in a cursive, flowing style.

Julian W. Woo
Primary Examiner

December 20, 2007